IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES**	

DEFENDANTS' REPLY IN SUPPORT OF MOTION TO LIMIT THE TESTIMONY OF PROF. DR. MED. UWE KLINGE

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this Reply in Support of their Motion to Exclude the Opinions and Testimony Prof. Dr. med. Uwe Klinge [Doc. **[**2762**]** ("Motion")] and Memorandum of Law in Support [Doc. **[**2765**]** ("Mem.")]. Ethicon requests that the Court grant its Motion and reject the arguments raised in Plaintiffs' Response to the Motion [Doc. 2960**]** ("Response")].

INTRODUCTION

Plaintiffs served two Rule 26 expert reports prepared by Dr. Klinge, one concerning the PROLENE* Mesh used in mid-urethral slings manufactured by Ethicon ("Klinge SUI Report") and a second relating to the PROLENE* Soft Mesh used in Ethicon's pelvic organ prolapse products ("Klinge Prolapse Report"). Following Dr. Klinge's lead, Ethicon distinguished his opinions regarding PROLENE* from his opinions regarding PROLENE* Soft, challenging the reliability of each based on the support provided in his separate reports and in his depositions concerning each mesh.

In response, Plaintiffs haphazardly cite prior opinions from this Court involving an SUI product as conclusive support for the reliability of Dr. Klinge's opinions regarding a prolapse product, and *vice versa*. Plaintiffs also assume that any support Dr. Klinge provides for his opinions regarding one set of products applies equally to his opinions regarding the other.

But PROLENE* and PROLENE* Soft are distinct, and those distinctions make a difference. The meshes have different pore sizes and weights, two design characteristics at the heart of Dr. Klinge's opinions. When the reliability of Dr. Klinge's opinions against each mesh is assessed individually—as it should be—it becomes clear that many of his opinions simply lack any support. For that reason, and for the other reasons set forth below, Ethicon's motion to limit Dr. Klinge's testimony should be granted.

ARGUMENT

I. Dr. Klinge should not be permitted to testify about alternatives to PROLENE* Soft because he did not reliably support any such opinion in his Prolapse Report.

In the August 24, 2016 order [Doc. 2642] granting in part, denying in part, and reserving in part Ethicon's Wave 1 *Daubert* motion regarding Dr. Klinge, the Court found that "Dr. Klinge's expert testimony about polyvinylidene fluoride ("PVDF") mesh" was sufficiently reliable for purposes of *Daubert*, citing as support its order in *Lewis*. *See In re Ethicon, Inc.*, No. 2:12-md-2327, 2016 WL 4473446, at *2 (S.D. W. Va. Aug. 24, 2016) (hereinafter "*Wave 1* Order"). In so ruling, the Court did not distinguish between Dr. Klinge's Prolapse Report and his SUI Report. But that distinction makes all the difference.

Although Ethicon continues to challenge the reliability of Dr. Klinge's opinion that PVDF is a better alternative for treatment of SUI, Dr. Klinge has at least pointed the Court in his SUI Report to literature regarding PVDF as a surgical mesh used to treat hernias. *See* Klinge SUI Report (attached as Ex. B to Ethicon's motion) at 37 (citing studies by Klink, Silva, and others

examining surgical mesh made of PVDF). In his Prolapse Report, however, Dr. Klinge does not identify a single study to support his opinion that PVDF is likewise a feasible alternative for treatment of pelvic organ prolapse.

To be clear, the *only* time Dr. Klinge references PVDF in his entire Prolapse Report is page 16, where he states, "The PVDF product, Dynamesh, is a safer design than Gynemesh PS [i.e., PROLENE* Soft Mesh] for all of the reasons stated above as further established in Muehl's testing." Klinge Prolapse Report (attached as Ex. C to Ethicon's motion) at 16. Yet Dr. Klinge does not identify in his Prolapse Report *any* reason why mesh made of PVDF is supposedly safer than Ethicon's chosen mesh. If ever there was *ipse dixit* by an expert witness, this is it.

Not only are the reasons for Dr. Klinge's opinion absent, so too is any supporting literature. Plaintiffs claim that "Dr. Klinge references numerous peer-reviewed articles that support his opinions regarding PVDF as an alternative design to Gynemesh PS." Pls.' Resp. 12. But nowhere in the actual Prolapse Report does Dr. Klinge reference any literature supporting his statement that PVDF is safer than polypropylene for treatment of prolapse. The articles Plaintiffs cite appear only in his *curriculum vitae* with no explanation as to how, if at all, they support his opinion.

Because of the differences between his SUI Report and Prolapse Report, this Court's ruling in *Lewis*—which examined the reliability of Dr. Klinge's opinions regarding alternatives for treatment of SUI—is inapposite. Instead, the Court should be guided by its ruling in *Bellew*, rendered after *Lewis* in a case involving a prolapse product and a report by Dr. Klinge that was identical to his current Prolapse Report. *See* Mem. Op. & Order [Doc. 265] at 16-17, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014).

In *Bellew*, the Court observed that "Dr. Klinge fails to cite *any* peer-reviewed studies" to

support his opinions on alternative design. *Id.* Because Dr. Klinge provided "no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon documents," which were "not sufficiently reliable scientific bases under *Daubert*," the Court precluded him from testifying about safer alternatives. *Id.*

Dr. Klinge's Prolapse Report is identical to the report at issue in *Bellew*. The Court should again preclude Dr. Klinge from testifying about alternative designs to Ethicon's prolapse products.[1]

II. Dr. Klinge should not be permitted to testify about alternative designs to PROLENE* in Ethicon's SUI products.

Dr. Klinge cannot identify any scientific testing or literature that shows that Ethicon's SUI products would be both safer and equally effective if it were made of Ultrapro or PVDF. Because there is no such testing or literature, his opinions on alternative designs should be excluded.

A. Ultrapro

Plaintiffs' claim that a mesh like Ultrapro—which has some absorbable fibers—would work in a device to treat SUI is inherently speculative. Neither Dr. Klinge nor the Plaintiffs have ever made a midurethral sling out of Ultrapro and tested it, not even in a cadaver. And when Ethicon tried to make a device out of a mesh like Ultrapro, TVTO-PA, the FDA refused in 2011 to allow it to be marketed because there was inadequate evidence to support the safety and effectiveness necessary for clearance. When the device flunked Ethicon's cadaver tests, it ended

[1] Plaintiffs did not respond to Ethicon's argument that Dr. Klinge should not be permitted to testify that a lighter-weight, larger-pore mesh would be a safer alternative to treat pelvic organ prolapse. As a result, even if the Court does not follow its ruling in *Bellew* and allows Dr. Klinge to testify about PVDF as an alternative to PROLENE* Soft, the Court should exclude any testimony about lighter-weight, larger-pore mesh as an alternative design.

the project. Plaintiffs' experts have many theories about why a larger pore mesh might be safer, but they have no evidence that it would be effective.[2] There is a difference between window screen and chicken wire.

Plaintiffs contend that Dr. Klinge has a reliable basis for his opinion that Ultrapro mesh is a safer alternative design, citing as support a 2013 journal article by Okulu about a single experiment in Turkey.[3] Although the Okulu article—which is the only source Dr. Klinge has identified to support his opinion that Ultrapro might actually be effective in treating stress urinary incontinence—did involve a comparison of Ultrapro and PROLENE*, the authors of that study employed a different surgical technique described as a "double-forced sling." *See* Okulu et al., *supra.* at 217–224. The surgery was different, the method of implantation was different, and the operation, unlike the TVT devices, required a general anesthetic and overnight stay in the hospital.

Furthermore, the authors of the Okulu study acknowledged that "[t]his surgical method also *needs evaluation*, especially in comparison with the traditional TVT sling procedure." *Id.* at 223. Because the study did not involve the same surgical technique as the sling devices manufactured by Ethicon, Dr. Klinge cannot rely on that study as support for his opinion that Ethicon's devices would be safer if Ethicon used Ultrapro rather than PROLENE* mesh.

Dr. Klinge admitted as much in deposition, testifying that he believes Ultrapro is safe and effective when used in the manner described in the Okulu article, but not if it were to be used in

[2] TVT mesh has the largest pore size of any mesh sold to treat SUI in the United States (and perhaps, the world).

[3] Okulu et al., *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, 47 SCANDINAVIAN J. UROLOGY 217 (2013) (attached as Ex. 7 to Pls.' Response).

the same manner PROLENE* mesh is used in Ethicon's devices:

> That the treatment has to be – you have to differentiate in what form you want to have it. If you're using the ULTRAPRO to – to serve as a ligament, as the PROLENE is intended to use, then you have the problem of the pore collapse. So the large-pore ULTRAPRO becomes a small-pore mesh device with all the risks.
>
> If you use it like the Turkish people [i.e., the authors of the Okulu study], and in fact at that time point I didn't have the idea that someone is using it in a different way. If you are using it to reinforce the tissues, as we did it with the flat meshes, then you don't have the risk for pore collapse, as with the ligaments, and with this procedure maybe it is a good idea to have it. *But to use it as a ligament it's not a good idea, and as a ligament I don't want to have it.*

Mot. Ex. G, Klinge 11/4/15 Dep. Tr. 285:5–20 (emphasis added). And his opinion as to "safety" simply ignores the more extensive anesthesia, surgery, and hospital stay the patients in the Okalu study had to endure.

In short, Okulu, which did not involve a TVT device, does not stand for the proposition that Ultrapro, when employed like the PROLENE* mesh in Ethicon's TVT devices, is safe and effective at treating stress urinary incontinence. As a result, Dr. Klinge is "not able to predict" whether "in the specific function of a sling the Ultrapro really over the time will work really better or whether it will create some new problems." Mot. Ex. D, Klinge 10/5/15 Dep. Tr. 92:17–93:4. The Court should preclude him from offering any opinions he admits are speculative.

Finally, Plaintiffs ask the Court to disregard Dr. Klinge's prior testimony that Ultrapro is subject to the same criticisms he levies against PROLENE*. But Dr. Klinge has repeatedly and steadfastly testified that Ultrapro is neither safe nor effective at treating stress urinary incontinence when implanted in the same manner as PROLENE* mesh in TVT. *See id.* (testifying that using Ultrapro the way PROLENE* mesh is intended to be used is "not a good idea" because it "becomes a small-pore mesh device with all the risks"); *see also* Mot. Ex. E,

Klinge 11/15/13 Dep. Tr. 529:12–23 (testifying that Ultrapro "is not sufficient to withstand—or to preserve the big pores—under these conditions of biomechanics as it is required for the use as a sling"). The jury should not be permitted to hear testimony Dr. Klinge has admitted for years is untrue.

B. PVDF

Although Dr. Klinge attempts to provide support for his opinion that PVDF is a safer alternative to PROLENE* for the treatment of SUI, Plaintiffs cannot overcome the fact that Dr. Klinge has never examined whether PVDF is subject to the same deficiencies he identifies in PROLENE*. *See* Mot. Ex. D, Klinge 10/5/15 Dep. Tr. 95:15-24 (testifying he does not know whether PVDF is subject to particle loss).

Dr. Klinge has also failed to identify any peer-reviewed literature showing that PVDF is equally effective as PROLENE* in the treatment of stress urinary incontinence, instead relying on studies examining hernia mesh. His opinion should be excluded as unreliable.

III. Dr. Klinge has identified no reliable basis for his opinion that PROLENE* Soft Mesh in Ethicon's prolapse products frays and loses particles.

Plaintiffs do not dispute that the PROLENE* Mesh in Ethicon's TVT family of products and the PROLENE* Soft Mesh in its pelvic organ prolapse products have different designs, including different pore sizes and different weights. Plaintiffs also ignore a key distinction in the manufacturing process: whereas PROLENE* Mesh can be cut mechanically, PROLENE* Soft is cut ultrasonically.

Because of these distinctions, Dr. Klinge's reliance on internal company documents relating to the TVT—a midurethral sling that uses PROLENE* Mesh rather than PROLENE* Soft—and a 2003 study about the TVT do not support his opinion that PROLENE* Soft frays and loses particles. Dr. Klinge is making an unfounded assumption that what happens to the

mesh in TVT must also happen to the mesh in Ethicon's prolapse products. Insofar as these TVT-related materials are the only materials Dr. Klinge cites in his report, he should be precluded from testifying at trial about PROLENE* Soft mesh fraying or losing particles.

Recognizing the shortcomings in Dr. Klinge's report, Plaintiffs in their response cite as additional support a peer-reviewed article by Dr. Klinge and colleagues that is referenced in his Prolapse Report and one page of what appears to be a PowerPoint slide referencing the same study by Dr. Klinge. Neither Plaintiffs nor Dr. Klinge explain, however, how this study—which concerns elongation of under load—supports his opinion that PROLENE* Soft Mesh is subject to fraying and particle loss. Plaintiffs bear the burden of "com[ing] forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 516 (S.D. W. Va. 2014). Surely they cannot satisfy that burden simply by citing, without any explanation, a single article.

CONCLUSION

WHEREFORE, FOR THESE REASONS and as more fully set forth in Ethicon's motion and supporting memorandum of law, Ethicon respectfully requests that this Court enter an order granting its Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on October 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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